

D1  
B4  
cons

- c. about 0.5 to about 4 parts by weight of diazolidinyl urea (DU);  
and  
d. about 0.1 to about 2 parts by weight of a halide salt.

### Remarks

In the Office Action mailed September 14, 2001 and made final, the Examiner rejected claims 1,5,9-11 and 35-40 under 35 U.S.C. 103 as allegedly unpatentable over Young et al (Pat. No. 5,529,933) in view of Ryan (Pat. No. 5,460,797).

Applicant believes that the Examiner has misapprehended the teachings of the respective references. However, in the interest of expediting prosecution to secure allowable subject matter, Applicant has amended the pending independent claims and has submitted proposed new claim 41. Specifically, the nature of the amendments are to point out that the present composition is a reagent for contacting fresh whole blood in the course of conducting a flow cytometric analysis of the blood. Applicants also have incorporated relative proportions of the ingredients. Young certainly fails to teach provide any motivation for the selection of such proportions, in a single mixture<sup>1</sup>, especially in combination with all of the recited components (certain of which the Examiner acknowledges are absent from Young). In short, the present amendments are believed to further distinguish the claimed invention relative to the art cited. Withdrawal of the rejection is therefore respectfully requested.

The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

### Conclusions

In view of Applicant's amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicant submits

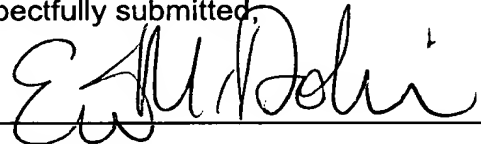
<sup>1</sup> Young does not appear to provide any teaching of a mixture of both a lysing agent and a lipoprotein for treating a sample of fresh human whole blood. At best, Young arguably discloses treatment of cells with a lipoprotein followed by contact of the cells with a lysing agent. The discussion, however, is generally in the context of preparing leukocyte blood cell analogs by suspending washed red blood cells from a non-human source (e.g., goose or alligator cells; see col. 12, lines 52-55; and col. 8, lines 11-21).

that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 593-9900.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Dated: Dec. 12, 2001

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Eric M. Dobrusin", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

*- new matter*  
1. (Twice Amended) A reagent system [composition] for preparing leukocytes for cytometric analysis, comprising:

a. a sample of fresh human whole blood upon which a cytometric analysis is to be performed while said fresh blood is still fresh;

b. a lipoprotein;

[b] c. an agent for lysing erythrocytes from said [a] sample of fresh blood for permitting cytometric analysis of said leukocytes; and

[c] d. a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.

5. (Twice Amended) A system for flow cytometry, comprising:

a. a flow cytometer instrument;

b. a reagent for preparing leukocytes for analysis by flow cytometry, said reagent including a mixture of:

i. about 5 to about 100 mg/dl of a lipoprotein;

ii. about 10 to about 300 mg/dl of an agent for lysing erythrocytes for permitting cytometric analysis of said leukocytes; and

iii. about 1 to about 6 gm/dl of a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.

39. (Once Amended) A reagent composition for preparing leukocytes for cytometric analysis, comprising:

a. about 0.01 to about 5 parts by weight of a high density lipoprotein;

b. about 0.1 to about 2 parts by weight of an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and

c. up to about 5 parts by weight of a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.

112/2)

composition  
"many parts"

system =  
many composition

different proportions

type?

40. (Once Amended) A reagent composition for preparing leukocytes for cytometric analysis, comprising a mixture of:

- a. about 0.01 to about 5 parts by weight of a high density lipoprotein;
- b. about 0.1 to about 2 parts by weight of an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and
- c. up to about 5 parts by weight of diazolidinyl urea (DU).

41. (New) A reagent composition for preparing leukocytes for cytometric analysis, comprising a mixture of:

- a. about 0.1 to about 1 part by weight of a high density lipoprotein;
  - b. about 0.3 to 1.5 parts by weight of an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and
  - c. about 0.5 to about 4 parts by weight of diazolidinyl urea (DU);
- and
- d. about 0.1 to about 2 parts by weight of a halide salt.